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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/475,721
Filing Date: December 30, 1999
Appellant(s): REIMINK ET AL.

Hallie A. Funicane
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/21/07 appealing from the Office action mailed 12/14/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct. It is noted that what Appellant has called "ground A" (claims 1-3, 8-9 as being anticipated by Reul) and "ground C" (claims 10-11, 16-19 as being anticipated by Reul)

were grouped together in one rejection, and that "ground B" (claims 5-7, 31, 32, dependent on claim 1, as being obvious over Reul and further in view of Pietsch) and "ground D" (claims 12-14, dependent on claim 10, as being obvious over Reul and further in view of Pietsch) were grouped together in a second rejection in the Office action dated 04/27/06. Appellant has separated the first rejection into Groups A and C, and the second rejection into Groups B and D in the argument section of the Appeal Brief. Hence the examiner has done the same below for clarity.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 4,263,680	REUL	4-1981
US 4,778,461	PIETSCH	10-1988
US 4,597,767	LENKEI	7-1986
JP 59,192,366 A (abstract)	SUMIMOTO	4-1983

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claims 1-3, 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Reul (US 4,263,680).

Regarding claim 1, Reul teaches a medical device (prosthetic heart valve, column 6, line 29) comprising a composite (valve member 1, column 5, line 41, Fig. 3) having an inorganic substrate (metal substrate 12, column 5, lines 45-47, Fig. 3) and a polymer applied on all of the substrate surfaces (blood compatible synthetic material 14, column 5, lines 41-44, Fig. 3 shown below), the polymer forming a structure shaped differently from the structure of the substrate, and providing the form of the device (Fig. 3, hinge flap 7 is formed in one piece with the valve member and consists of the same blood-compatible synthetic material with which the valve member is coated, integrally cast in the course of the coating process, column 4, lines 39-45, valve ring is coated with the same blood-compatible synthetic material as the valve member, column 4, lines 47-49).

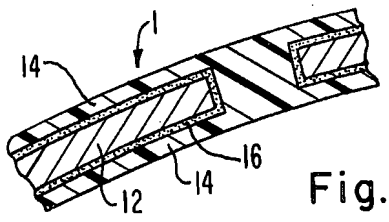

Fig. 3

Regarding claim 2, Reul teaches that the substrate comprises metal (column 5, lines 45-47).

Regarding claim 3, Reul teaches that the substrate comprises a ceramic (column 4, lines ceramic used instead of metal, column 4, lines 18-24).

Regarding claim 8, Reul teaches that the medical device comprises a heart valve prosthesis (prosthetic heart valve, column 6, line 29), the heart valve prosthesis comprising a component (valve member 1, column 5, line 41, Fig. 3) that comprises the composite having the inorganic substrate metal substrate 12, column 5, lines 45-47, Fig. 3) and the polymer material (blood compatible synthetic material 14, column 5, lines 41-44, Fig. 3).

Regarding claim 9, Reul teaches that the polymer material has structure forming a slot (valve ring is provided with a slot, column 5, lines 30-32, valve ring is coated with the same blood-compatible synthetic material as the valve member, column 4, lines 47-49).

B. Claims 5-7, 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reul as applied to claims 1-3, 8-9 above, and further in view of Pietsch (US 4,778,461).

Reul teaches the heart valve prosthesis comprising the composite having an inorganic substrate and a polymer applied on all of the substrate surfaces, covering the substrate, as described above.

Regarding claims 5, 32, Reul fails to teach that the polymer is polyethersulfone or polycarbonate.

However, Pietsch teaches a heart valve prosthesis (abstract), wherein the polymer is polyethersulfone or polycarbonate, for the purpose of providing a physiologically acceptable material (column 3, lines 45-55). Polycarbonate is a rigid polymer by virtue of its composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used polyethersulfone, or polycarbonate which is a rigid polymer, as the polymer of Reul, in order to provide a physiologically acceptable material for the heart valve prosthesis, as taught by Pietsch.

Regarding claims 6-7, Reul fails to teach the thickness of the polymer member.

However, Pietsch teaches that the wall thickness of the polymer can be 50 to 1000 microns (column 2, lines 50-55), which is within the claimed range of at least about 10 microns, overlaps the claimed range of from about 100 microns to about 2000 microns, and of from about 10 microns to about 500 microns, and encompasses the claimed range of from about 50 microns to about 300 microns, for the purpose of providing the desired Shore hardness and breaking strength of the flexible material (column 2, lines 50-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the polymer member of Reul with a thickness within the claimed ranges, in order to provide the desired Shore hardness and breaking strength for the flexible polymer member, as taught by Pietsch.

Regarding claim 31, Reul fails to teach that the polymer is polyurethane or polydimethylsiloxane, or that it is crosslinked.

However, Pietsch teaches a heart valve prosthesis (abstract) wherein the polymer is polyurethane for providing blood compatibility (column 4, lines 34-40) as well as polydimethylsiloxane (column 5, lines 5-10, silicone rubber, column 4, lines 54-65),

which is crosslinked for the purpose of providing flexibility coupled with high breaking strength (column 4, lines 21-26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used polyurethane or polydimethylsiloxane, as the polymer of Reul, in order to provide blood compatibility, and to have cross-linked it, in order to provide flexibility coupled with high breaking strength, to the heart valve prosthesis, as taught by Pietsch.

C. Claims 10-11, 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Reul (US 4,263,680).

Regarding claim 10, Reul teaches a medical device prosthetic heart valve, column 6, line 29) comprising a composite component comprising an inorganic substrate (metal substrate 12, column 5, lines 45-47, Fig. 3) and a polymer member covering the substrate (blood compatible synthetic material 14, column 5, lines 41-44, Fig. 3 shown on the next page), wherein the composite component can be bent through a cross section of the composite component (thin valve member including metal substrate can be bent, 03-0.4 mm, column 3, lines 40-45), and wherein the polymer member contacts bodily fluids and separates the bodily fluids from the substrate (blood-compatible synthetic material, column 4, lines 40-45). The composite component is flexible by virtue of its thickness (less than 0.3 – 0.4 mm, column 3, lines 40-42), and its composition (thin metal substrate, 5, lines 45-46, and coating of blood compatible synthetic material, column 5, lines 41-44, which is flexible, flap made from the same, column 6, lines 44-46, column 4, lines 39-45).

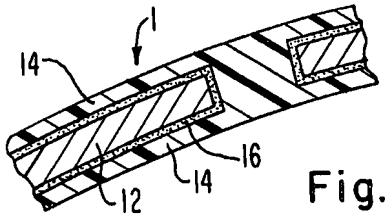

Fig. 3

Regarding claim 11, Reul teaches that the heart valve member is preferably less than 300 microns (0.3 mm, column 3, lines 40-50), meaning that the metal substrate is a metal foil which has a thickness of less than 300 microns, which is within the claimed thickness range of less than about 500 microns.

Regarding claims 16-17, the flexible composite component of Reul is expected to have the ability to be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the flexible composite component beyond its elastic limit, by virtue of its composition (metal substrate, 5, lines 45-46, and coating of blood compatible synthetic material, column 5, lines 41-44, which is flexible, flap made from the same, column 6, lines 44-46, column 4, lines 39-45).

Regarding claims 18-19, Reul teaches that the number of stress cycles completed up to March 3, 1978 was 98 million with no appearance of fatigue (column 6, lines 14-23). Thus the flexible composite component of Reul is expected to have the ability to be bent about 60 degrees for about 40 million cycles without significant structural failure. Reul teaches that the life span aimed at is 367 million stress cycles at normal frequency (column 6, lines 20-23), which is within the range of about 400 million cycles without significant structural failure.

D. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reul as applied to claims 10-11,16-19 above, and further in view of Pietsch (US 4,778,461).

Reul teaches the heart valve prosthesis comprising the composite having an inorganic substrate and a polymer applied on all of the substrate surfaces, covering the substrate, as described above.

Regarding claim 12, Reul fails to teach that the polymer is polyurethane or polydimethylsiloxane, or that it is crosslinked.

However, Pietsch teaches a heart valve prosthesis (abstract) wherein the polymer is polyurethane for providing blood compatibility (column 4, lines 34-40) as well as polydimethylsiloxane (column 5, lines 5-10, silicone rubber, column 4, lines 54-65), which is crosslinked for the purpose of providing flexibility coupled with high breaking strength (column 4, lines 21-26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used polyurethane or polydimethylsiloxane, as the polymer of Reul, in order to provide blood compatibility, and to have cross-linked it, in order to provide flexibility coupled with high breaking strength, to the heart valve prosthesis, as taught by Pietsch.

Regarding claims 13-14, Reul fails to teach the thickness of the polymer member.

However, Pietsch teaches that the wall thickness of the polymer can be 50 to 1000 microns (column 2, lines 50-55), which is within the claimed range of at least

about 10 microns, overlaps the claimed range of from about 100 microns to about 2000 microns, and of from about 10 microns to about 500 microns, and encompasses the claimed range of from about 50 microns to about 300 microns, for the purpose of providing the desired Shore hardness and breaking strength of the flexible material (column 2, lines 50-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the polymer member of Reul with a thickness within the claimed ranges, in order to provide the desired Shore hardness and breaking strength for the flexible polymer member, as taught by Pietsch.

E. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reul as applied to claims 1-3, 8-11, 16-19 above, and further in view of Lenkei (US 4,597,767).

Reul teaches that the medical device comprises a heart valve prosthesis (prosthetic heart valve, column 6, line 29) comprising a composite component comprising an inorganic substrate and a polymer member covering the substrate, as described above, but fails to teach that the composite component comprises leaflets.

However, Lenkei teaches a medical device which comprises a heart valve prosthesis (column 4, lines 39-45) comprising a flexible composite component comprising leaflets, wherein each leaflet comprises an inorganic substrate which comprises a metal foil (stainless steel, column 4, lines 19-25). The flexible component can be bent through a cross section of the flexible component (stainless steel foil).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the heart valve composite component of

Reul with leaflets, in order to provide the desired heart valve prosthesis, as taught by Lenkei.

F. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reul, as applied to claims 1-3, 8-11, 16-19 above, and further in view of Sumitomo Electric Co. (Abstract, JP 59192366).

Reul teaches the heart valve prosthesis comprising polymer member as described above, and fails to teach that the composite further comprises a diamond-like carbon coating over at least a portion of the polymer member.

However, Sumimoto teaches a diamond-like carbon coating over the polymer member for the purpose of providing good antithrombosis and durability properties to the heart valve prosthesis (artificial heart valve, abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided a diamond-like carbon coating over at least a portion of the polymer member of the heart valve prosthesis of Reul, in order to obtain good antithrombosis and durability properties, as taught by Sumimoto.

(10) Response to Argument

A. 35 U.S.C. 102(b) rejection of claims 1-3, 8-9 as being anticipated by Reul.

1. Appellant argues that Reul teaches a dipping process to coat the polymer (biocompatible) onto the inorganic surface, and that a dipping process places a layer having a substantially uniform thickness onto the inorganic substrate that conforms to the general shape of the substrate, and that a coating of a substantially uniform thickness does not provide a structure that is shaped differently from the structure of the

substrate as claimed, and that thus, the polymer (synthetic coating) of Reul conforms to the shape of the [inorganic] substrate.

The Board is respectfully apprised that the embodiment of the composite structure of Reul in Fig. 3, shown below, is a medical device (prosthetic heart valve, column 6, line 29) comprising a composite 1(valve member 1, column 5, line 41, Fig. 3) wherein the encapsulating polymer 14, shaded with \\ (blood compatible synthetic material 14, column 5, lines 41-44), provides a structure that defines the form of the device, which is indeed shaped differently from the inorganic substrate 12, shaded with the reverse hatch // (metal substrate 12, column 5, lines 45-47), as defined by Appellant.

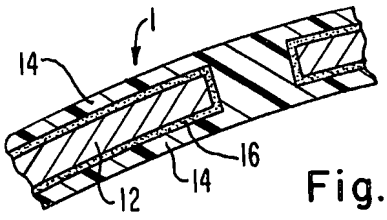

Fig. 3

The shape of a structure with spaces, is changed to one without spaces. Appellant discloses that when the polymer member smoothes edges and fills in spaces, it modifies the details of the substrate (specification, page 19, lines 27-29), hence defining the shape of the composite. Therefore, not only is the shape of the structure of the polymer in the device of Reul different from the shape of the structure of the substrate, it defines the shape of the composite, as interpreted in terms of Appellant's disclosure.

In addition, Reul teaches that the composite 1 has the shape of a dish (form, valve member 1, column 5, lines 8-10), and that the hinge flap is formed in one piece

with the valve member, consisting of the same polymer with which the valve member is encapsulated (column 4, lines 39-45), forming a composite structure that is different from the shape of the inorganic substrate 12. Appellant discloses that additional structure that does not result from simple application of a polymer material over the surface, note the adjective "additional", include barbs and anchors (specification, page 19, line 34, page 20, lines 1-4). Reul's hinge qualifies as an anchor. Therefore, as interpreted in terms of Appellant's disclosure, the shape of the structure of the polymer in the device of Reul is indeed different from the shape of the structure of the substrate, and additionally provides the form of the device.

2. Appellant argues that the Office makes reference to Fig. 3 [of Reul] which is a cross-section of the valve member taken along section line III-III in Fig. 1, wherein Fig. 3 illustrates a portion of the substrate having an aperture there through which enables the layers of polymer (synthetic material) on each side of the metal substrate to be interconnected, wherein in the finished valve member, these apertures are completely filled with synthetic material. Appellant argues that interconnections created by filling in the voids created by the apertures between the outer surfaces of the valve member do not affect the form of the device as claimed.

The Board is respectfully reminded that, as discussed above, Appellant discloses that when the polymer member smoothes edges and fills in spaces, it modifies the details of the substrate (specification, page 19, lines 27-29), hence defining the shape of the composite. Therefore, not only is the shape of the structure of the polymer in the

device of Reul different from the shape of the structure of the substrate, it also defines the shape of the composite, as interpreted in terms of Appellant's disclosure.

3. Appellant argues that referring to Fig. 2 of Reul, the outer surface of the polymer on valve member 1 has the same configuration as the outer surface of the metal surface 12, where it is clearly shown that the metal substrate is in the form of a cupped disc and that the polymeric material follows the form of the metal substrate also forming a cupped disc.

The Board is respectfully reminded that, as discussed above, composite 1(valve member 1, column 5, line 41, Fig. 3) wherein the encapsulating polymer 14, shaded with \\ (blood compatible synthetic material 14, column 5, lines 41-44), provides a structure that defines the form of the device, which is indeed shaped differently from the inorganic substrate 12, shaded with the reverse hatch // (metal substrate 12, column 5, lines 45-47), as defined by Appellant.

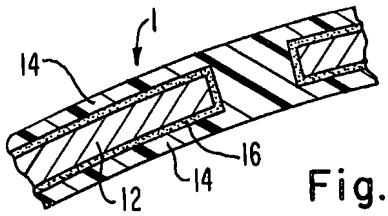

Fig. 3

The shape of a structure with spaces, is changed to one without spaces. Appellant discloses that when the polymer member smoothes edges and fills in spaces, it modifies the details of the substrate (specification, page 19, lines 27-29), hence defining the shape of the composite. Therefore, not only is the shape of the structure of the polymer in the device of Reul different from the shape of the structure of the substrate, it

also defines the shape of the composite, as interpreted in terms of Appellant's disclosure.

4. Appellant argues that Fig. 1 [of Reul] shows that hinge 4 as being internal to the construction of the heart valve, since it is not shown in the cross section shown in Fig. 2, and that as such, there is no evidence that the hinge [being internal] provides a form to the device as claimed.

The Board is respectfully apprised that the hinge flap 7 in the Office rejection is different from the hinge 4 argued by Appellant.

Furthermore, the Board is respectfully reminded that Reul teaches that the composite 1 has the shape of a dish (form, valve member 1, column 5, lines 8-10), and that the hinge flap 7 is formed in one piece with the valve member, consisting of the same polymer with which the valve member is encapsulated (advantageously formed in one piece with the valve member and consists of the same blood-compatible material, integrally cast so that it is connected with the valve member without transition, column 4, lines 39-45, in the area of the hinge 4, the valve member 1 is provided with a small flap of synthetic material 7 serving as a hinge and extending beyond the edge of the valve member 1, column 5, lines 20-27), forming a composite structure that is different from the shape of the inorganic substrate 12. Appellant discloses that additional structure that does not result from simple application of a polymer material over the surface, note the adjective "additional", include barbs and anchors (specification, page 19, line 34, page 20, lines 1-4). Reul's hinge flap qualifies as an anchor. Therefore, not only is the shape of the structure of the polymer in the device of Reul different from the

shape of the structure of the substrate, it also defines the shape of the composite, as interpreted in terms of Appellant's disclosure.

B. 35 U.S.C. 103(a) rejection of claims 5-7, 31-32 over Reul in view of Pietsch.

1. Appellant's arguments are directed against the valid use of the primary reference Reul, and are addressed above.

C. 35 U.S.C. 102(b) rejection of claims 10-11, 16-19 as being anticipated by Reul.

1. Appellant argues that Reul does not disclose a heart valve member that can be bent through a cross-section, or that it would flex.

The Board is respectfully apprised that Reul discloses that the composite is very thin (less than 0.3 – 0.4 mm, column 3, lines 40-42), and is thus a thin metal foil substrate in a flexible blood compatible synthetic material body (metal substrate, 5, lines 45-46, and coating of blood compatible synthetic material, column 5, lines 41-44, which is flexible, flap made from the same, column 6, lines 44-46, column 4, lines 39-45). Appellant discloses that a flexible component can include a thin metal foil or the like as the substrate with a flexible polymer material (specification, page 15, lines 25-30). Therefore, as interpreted in terms of Appellant's disclosure, the thin composite of Reul with a thickness that is less than 0.3 mm, formed of the thin metal foil substrate enclosed in the flexible polymer material, will flex, and hence can be bent through a cross-section. Furthermore, it is noted that anything is capable of being bent when enough force is applied.

2. Appellant argues that a reduction in weight of the valve member to decrease the moment of inertia does not lead to the conclusion that the valve member flexes, and

that if the valve member is flexed, then some of the force created by the pressure gradient would have to be directed into forcing the valve member to flex, thereby decreasing the responsiveness of the valve to the pressure gradient, where the decreased responsiveness is due to it being a two-step process: first flexing the valve member and then moving the valve member about a pivot, which is contrary to the responsiveness taught by Reul.

The Board is respectfully reminded that, as discussed above, Reul discloses that the composite is very thin, less than 300 microns as claimed by Appellant (less than 0.3 mm, column 3, lines 40-50), and is a thin metal foil substrate in a flexible blood compatible synthetic material body (thin metal substrate, 5, lines 45-46, and coating of blood compatible synthetic material, column 5, lines 41-44, which is flexible, flap made from the same, column 6, lines 44-46, column 4, lines 39-45). Appellant discloses that a flexible component can include a thin metal foil or the like as the substrate with a flexible polymer material (specification, page 15, lines 25-30). Therefore, as interpreted in terms of Appellant's disclosure, the thin composite of Reul with a thickness that is less than 300 microns, formed of the thin metal foil substrate enclosed in the flexible polymer material, is indeed flexible. Appellant has not specified the amount of force or pressure used to determine and hence distinguish the nature of the flexibility over the prior art. Furthermore, Appellant has not specified the location of the flexibility along the length of the composite (not just any cross-section) to distinguish the nature of the flexibility over the prior art.

3. Appellant argues that there is no disclosure that the heart valve of Reul flexes as it has substantially a different structure than a natural heart valve that opens and closes in a substantially different manner than a natural heart valve, and that as such, US 4,888,009 and US 5,500,016 are not applicable as further evidence that the heart valve of Reul is flexible since the structures of the valves are different.

The Board is respectfully apprised that US 4,888,009 (flexible leaflets of synthetic material somewhat like natural valves, column 1, lines 10-20) and US 5,500,016 (flexible leaflet valves mirror natural heart valves more closely, column 1, lines 23-25) are further evidence that the heart valve of Reul is flexible since Reul teaches that the valve resembles a natural valve more closely than any other existing artificial heart valve (column 3, lines 40-50). This additional evidence was produced when Appellant argued that there is no teaching in Reul that an artificial heart valve flexes (page 4 of Appellant's response dated 09/27/06.

4. Appellant argues that a natural heart valve has a distinctly different structure than the heart valve of Reul, where the natural heart valve has leaflets having edges that move away and contact each other to allow blood to flow through and not backflow, while the valve of Reul has a cup-shaped disc configuration that is hingedly attached to a vessel wall at one end and thus the flexing of the cup-shaped valve would reduce the response time of the valve and hinder its performance. Appellant further argues that in light of the fact that a member that flexes would consume more energy than would normally be used to move the cupped valve about its hinge, which is in direct

contradiction to Reul's disclosure, [the Office's position on the inherency of the flexibility of the heat valve of Reul is not sustainable].

The Board is respectfully reminded that, as discussed above, as interpreted in terms of Appellant's disclosure, the thin composite of Reul with a thickness that is less than 300 microns, formed of the thin metal foil substrate enclosed in the flexible polymer material, is inherently flexible. Appellant has not specified the amount of force or pressure used to determine and hence distinguish the nature of the flexibility over the prior art. Furthermore, Appellant has not specified the location of the flexibility along the length of the composite (not just any cross-section) to distinguish the nature of the flexibility over the prior art.

5. Appellant concludes that the Office has provided no evidence that the cup-shaped valve of Reul must inherently flex, and that rather, Reul teaches that it would be disadvantageous for the valve to have flexing capability.

The Board is respectfully reminded that as discussed above, as interpreted in terms of Appellant's disclosure, the thin composite of Reul with a thickness that is less than 300 microns, formed of the thin metal foil substrate enclosed in the flexible polymer material, must inherently flex. Appellant has not specified the amount of force or pressure used to determine and hence distinguish the nature of the flexibility over the prior art. Furthermore, Appellant has not specified the location of the flexibility along the composite (not just any cross-section) to distinguish the nature of the flexibility over the prior art.

D. 35 U.S.C. 103(a) rejection of claims 12-14 over Reul in view of Pietsch.

Appellant's arguments are directed against the valid use of the primary reference Reul, and are addressed above.

E. 35 U.S.C. 103(a) rejection of claim 15 over Reul in view of Lenkel.

Appellant's arguments are directed against the valid use of the primary reference Reul, and are addressed above.

F. 35 U.S.C. 103(a) rejection of claim 20 over Reul in view of Sumimoto.

Appellant's arguments are directed against the valid use of the primary reference Reul, and are addressed above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Sow-Fun Hon

Sow-Fun Hon

Conferees:

/Jennifer Michener/

Quality Assurance Specialist

Jennifer Michener

Rena Dye

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